

Image
1614



PTO/SB/21 (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

		Application Number	10/082,443
		Filing Date	February 22, 2002
		First Named Inventor	Mark R. ALVIS
		Art Unit	1614
		Examiner Name	A. Mohamed
Total Number of Pages in This Submission	11	Attorney Docket Number	437252001200

ENCLOSURES (Check all that apply)

<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	1. Communication (2 pages) 2. Duplicate of Information Disclosure Statement and PTO-1449 as filed May 9, 2002 (8 pages) 3. Return Postcard
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)		
<input type="checkbox"/> Response to Missing Parts/ Incomplete Application		
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		
Remarks		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	MORRISON & FOERSTER LLP (Customer No. 25226) Kimberly A. Bolin - 44,546	
Signature		
Date	March	, 2004

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 3/1/04

Signature: Mae Pattison (Mae Pattison)



I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 3/1/04 Signature: Mae Pattison
(Mae Pattison)

Docket No.: 437252001200
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Mark R. ALVIS et al.

Application No.: 10/082,443

Confirmation No.: 6302

Filed: February 22, 2002

Art Unit: 1614

For: METHODS AND COMPOSITIONS FOR
IMPROVED ARTICULAR SURGERY USING
COLLAGEN

Examiner: A. Mohamed

COMMUNICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to the voice mail message received from Examiner Abdel Mohamed, on February 25, 2004, we are submitting herewith a duplicate copy of the entire Information Disclosure Statement (IDS) and PTO-1449 as filed with the U.S. Patent and Trademark Office on May 13, 2002. Examiner Mohamed indicated to the Applicant that the IDS, PTO-1449 and references were received by the Office, with the exception of page 4 of the PTO-1449. Should the Examiner determine that any other of the materials submitted with the IDS are missing, duplicate copies will be provided upon request.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 437252001200.

Dated: March 1 , 2004

Respectfully submitted,

By _____

Kimberly A. Bolin

Registration No.: 44,546
MORRISON & FOERSTER LLP
755 Page Mill Road
Palo Alto, California 94304
(650) 813-5740



PATENT
Docket No. 437252001200

CERTIFICATE OF MAILING BY "FIRST CLASS MAIL"

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on May 9, 2002.


Barbara M. Weatherly

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Mark R. ALVIS et al.

Serial No.: 10/082,443

Filing Date: February 22, 2002

For: METHODS AND COMPOSITIONS FOR
IMPROVED ARTICULAR SURGERY
USING COLLAGEN

Examiner: To Be Assigned

Group Art Unit: 1614

INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 AND § 1.98

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO-1449. Copies of the documents are also submitted herewith. The Examiner is requested to make these documents of record.

This Information Disclosure Statement is submitted:

- With the application; accordingly, no fee or separate requirements are required.
- Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required.
- After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - A fee is required. A check in the amount of * is enclosed.
 - A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - A Certification under 37 C.F.R. § 1.97(e) is provided below; accordingly; no fee is believed to be due.
- After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - A Certification under 37 C.F.R. § 1.97(e) is provided below and a check in the amount of is enclosed.
 - A Certification under 37 C.F.R. § 1.97(e) is provided below and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.

Applicants would appreciate the Examiner initialing and returning the Form PTO-1449, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **437252001200**. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: May 9, 2002

Respectfully submitted,

By:



Kimberly A. Bolin
Registration No. 44, 546

Morrison & Foerster LLP
755 Page Mill Road
Palo Alto, California 94304-1018
Telephone: (650) 813-5740
Facsimile: (650) 494-0792

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>		Docket Number 437252001200	Application Number 10/082,443
		Applicant	Mark R. ALVIS et al.
		Filing Date: February 22, 2002	Group Art Unit: 1614
		Mailing Date: May 9, 2002	

O I P E U S A
MAR 03 2004
PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing Date If Appropriate
	1.	04/06/1976	3,949,073	Daniels et al.			
	2.	06/29/1976	3,966,908	Balassa			
	3.	02/20/1979	4,140,537	Luck et al.			
	4.	11/11/1980	4,233,360	Luck et al.			
	5.	02/10/1981	4,250,139	Luck et al.			
	6.	07/05/1983	4,391,749	Engvall et al.			
	7.	01/03/1984	4,424,208	Wallace et al.			
	8.	09/25/1984	4,473,551	Schinitsky			
	9.	04/15/1986	4,582,640	Smestad et al.			
	10.	10/27/1987	4,703,108	Silver et al.			
	11.	11/03/1987	4,704,273	McMichael			
	12.	07/26/1988	4,760,131	Sundsmo et al.			
	13.	08/16/1988	4,764,377	Goodson			
	14.	02/14/1989	4,804,745	Koepff et al.			
	15.	03/06/1990	4,906,670	Higashi et al.			
	16.	03/26/1991	5,002,071	Harrell			
	17.	07/30/1991	5,036,056	Kludas			
	18.	04/01/1997	5,616,689	Shenoy et al.			
	19.	06/17/1997	5,639,796	Lee			
	20.	07/04/2000	6,083,918	Klaus			
	21.	07/11/2000	6,087,355	Cho et al.			
	22.	12/26/2000	6,165,983	Klaus			
	23.	11/13/2001	6,316,015 B1	Rondelez et al.			
	24.	11/13/2001	6,316,033 B1	Lin			
	25.	11/27/2001	6,322,592 B2	Lucas et al.			

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449 INFORMATION DISCLOSURE CITATION IN AN APPLICATION <i>(Use several sheets if necessary)</i>				Docket Number 437252001200	Application Number 10/082,443		
				Applicant	Mark R. ALVIS et al.		
				Filing Date: February 22, 2002	Group Art Unit: 1614		
				Mailing Date: May 9, 2002			

	26.	12/06/2001	Application No. 20010049366	Singh et al.			
	27.	01/10/2002	Application No. 20020004499	Rudnic et al.			

FOREIGN PATENT DOCUMENTS

Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Translation YES NO
	28.	10/25/1989	EP 338813	EPO			
	29.	11/1981	SU 880426	Russia			X (Abstract)

OTHER DOCUMENTS*(including author, title, Date, Pertinent Pages, Etc.)*

Examiner Initials	Ref. No.	Title
	30.	Altman, R. D. (1992) "Laboratory Findings in Osteoarthritis" Chapter 12 <i>In Osteoarthritis: Diagnosis and Medical/Surgical Management</i> , Moskowitz, Howell, Goldberg and Mankin, Eds., WB Saunders Co., Harcourt Brace Jovanovich, pp. 313-328.
	31.	Balazs, E.A. and Denlinger, J. L. (1989). "Clinical Uses of Hyaluronan" <i>In Biology of Hyaluronan</i> , John Wiley & Sons, 143:265-275.
	32.	Batyrov, T.U. et al. (March-April 1982). "Experimental Study of the Local Anesthetic Action of Trimecaine Prolonged with Collagen," <i>Stomatologiya</i> 61(2): 7-10. (English Abstract).
	33.	Bentz, H. et al. (1998). "Improved Local Delivery of TGF- β 2 by Binding to Injectable Fibrillar Collagen Via Difunctional Polyethylene Glycol," <i>J. Biomed. Mater. Res.</i> 39:539-548.
	34.	Brahn, E. (April 1991). "Animal Models of Rheumatoid Arthritis: Clues to Etiology and Treatment," <i>Clin. Orthop. and Related Research</i> . 265:42-53.
	35.	Capaldi, M. J. and Chapman, J.A. (1982). "The C-Terminal Extrahelical Peptide of Type I Collagen and Its Role in Fibrillogenesis <i>In Vitro</i> ," <i>Biopolymers</i> 21:2291-2313.
	36.	Carron, H. (April 1978). "Relieving Pain with Nerve Blocks," <i>Geriatrics</i> 49-52,57.
	37.	Cepeda, M. S. et al. (1997). "Pain Relief After Knee Arthroscopy: Intra-Articular Morphine, Intra-Articular Bupivacaine, or Subcutaneous Morphine," <i>Reg. Anesth.</i> 22(3):223-238.
	38.	Cooperman, L. et al. (1984). "The Immunogenicity of Injectable Collagen I. a 1-Year Prospective Study," <i>J. of the Am. Acad. Dermatol.</i> 10:638-646.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449

INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

MAR 03 2004

PATENT & TRADEMARK OFFICE

Docket Number 437252001200

Application Number 10/082,443

Applicant

Mark R. ALVIS et al.

Filing Date: February 22, 2002

Group Art Unit: 1614

Mailing Date: May 9, 2002

- | | | |
|--|-----|---|
| | 39. | Creamer, P. et al. (1996) "Pain Mechanisms in Osteoarthritis of the Knee: Effect of Intraarticular Anesthetic," <i>The J. of Rheumatol.</i> 23:1031-1036. |
| | 40. | De Andres, J. et al. (1998). "Intra-Articular Analgesia After Arthroscopic Knee Surgery: Comparison of Three Different Regimens," <i>Eur. J. of Anaesth.</i> 15:10-15. |
| | 41. | Debruyne, D. et al. (1985). Monitoring Serum Bupivacaine Levels During Arthroscopy," <i>Eur. J. of Clin. Pharmacol.</i> 27:733-735. |
| | 42. | DeLustro, F. et al. (1987). "Reaction to Injectable Collagen: Results in Animal Models and Clinical Use," <i>Plast. Reconstruct. Surg.</i> 79:581-592. |
| | 43. | DeLustro, F. et al. (July 1988). "Immunity to Injectable Collagen and Autoimmune Disease: A Summary of Current Understanding," <i>Dermatol. Surg. Oncol.</i> 14(Suppl. 1)(7):57-65. |
| | 44. | Frank, D. H. et al. (June 1991). "Human Antibody Response Following Multiple Injections of Bovine Collagen," <i>Plast. Reconstruct. Surg.</i> 87(6):1080-1088. |
| | 45. | Fraser, R. E et al. (June 1993). "The Kinetics of Hyaluronan in Normal and Acutely Inflamed Synovial Joints: Observation With Experimental Arthritis in Sheep," <i>Sem. Arthritis and Rheumatism</i> 22(6)(Suppl. 1):9-17. |
| | 46. | Frizziero, L et al. (1998). "Intra-Articular Hyaluronic Acid in the Treatment of Osteoarthritis of the Knee: Clinical and Morphological Study," <i>Clin. and Exp. Rheumatol.</i> 16:441-449. |
| | 47. | Gelman, R. A et al. (November 1979). "Collagen Fibril Formation <i>In Vitro</i> ," <i>J. Biol. Chem.</i> 254:11741-11745. |
| | 48. | Gradinger, R. et al. (June 1995). "Influence of Various Irrigation Fluids on Articular Cartilage," <i>Arthroscopy: The Journal of Arthroscopic and Related Surgery</i> 11(3):263-269. |
| | 49. | Henderson , R. C. et al. (1990). "Postarthroscopy Analgesia with Bupivacaine: A Prospective, Randomized, Blinded Evaluation," <i>The Am. J. of Sports Med.</i> 18(6):614-617. |
| | 50. | Horakava, P. Z. et al. (1967). "Prolongation Par Les Substances Collagènes De Therapie 22(6): 1455-1460. (English Abstract) |
| | 51. | Kaeding, C. et al. (1990). "Bupivacaine Use After Knee Arthroscopy: A Pharmacokinetics and Pain Control Study," <i>Arthroscopy: The Journal of Arthroscopic and Related Surgery</i> 6(1):33-39. |
| | 52. | Konobevtsev , O. et al. (1982). "Local Anesthetic Effect of Trimecaine Prolonged by Collagen," <i>Stomatologiya</i> 61(5): 7-9. (English Abstract). |
| | 53. | Konobevtsev et al. (1986). "New Drug Forms of the Local Anesthetic Pyormecaine," <i>Anaesteziol Reanimatol</i> 0(3): 50-52. (English Abstract) |
| | 54. | Kroesen, S. et al. (2000). "Induction of an Acute Attack of Calcium Pyrophosphate Dihydrate Arthritis by Intra-Articular Injection of Hylan G-F 20 (Synvisc). <i>Clin. Rheumatol.</i> 19:147-149. |
| | 55. | Mah, E. T. et al. (1991). "Effects of Irrigation Fluid on Human Menisci: An Experimental Comparison of Water, Normal Saline and Glycine," <i>The Journal of Arthroscopic and Related Surgery</i> 7(1):24-32. |

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

Form PTO-1449

P INFORMATION DISCLOSURE CITATION
IN AN APPLICATION

(Use several sheets if necessary)

MAR 03 2004
PATENT & TRADEMARK OFFICE

Docket Number 437252001200

Application Number 10/082,443

Applicant

Mark R. ALVIS et al.

Filing Date: February 22, 2002

Group Art Unit: 1614

Mailing Date: May 9, 2002

56. Marshall, G. J. et al. (1988). "Synovisol as an Irrigant for Electrosurgery of Joints," *Arthroscopy: The Journal of Arthroscopic and Related Surgery* 4(3):187-193.
57. Marshall, K.W. et al. (2000). "Amelioration of Disease Severity by Intraarticular Hylan Therapy in Bilateral Canine Osteoarthritis," *The J. of Orthop. Res.* 18:416-425.
58. McCain, J. P. et al. (1989). "Preliminary Studies on the Use of a Viscoelastic Solution in Arthroscopic Surgery of the Temporomandibular Joint," *J. Oral Maxillofac. Surg.* 47:1161-1168.
59. McPherson, J. M. et al. (1988). "The Effects of Heparin on the Physicochemical Properties of Reconstituted Collagen," *Coll. Relat. Res.* 8(1):65-82.
60. Meinig, R. P. et al. (1988). "Plasma Bupivacaine Levels Following Single Dose Intraarticular Instillation for Arthroscopy," *The Am. J. of Sports Med.* 16(3):295-300.
61. Moya, F. (1981). "Treatment of Osteoarthritis of the Spine and Herpetic Neuralgia at the Pain Center, Mount Sinai Medical Center" *In New Approaches to Treatment of Chronic Pain: A Review of Multidisciplinary Pain Clinics and Pain Centers.* Ng, L. K.Y. ed., 36: 118-121.
62. Myers, L. K . et al. (1997). "Collagen-Induced Arthritis, An Animal Model of Atoimmunity," *Life Sci.* 61(19):1861-1878.
63. Noyes, F. R. and Westin-Barber, S. D. (February 1997). "Arthroscopic-Assisted Allograft Anterior Cruciate Ligament Reconstruction in Patients With Symptomatic Arthrosis," *Arthroscopy: The Journal of Arthroscopic and Related Surgery* 13(1):24-42.
64. Pavelka, K. et al. (June 1999). "Pain Reduction in Knee Osteoarthritis: A Novel Treatment Using Intra-articular Type I Collagen NeuVisc™ Synovial Fluid Supplement," Presented at *4th Congress of the European Federation of National Associations of Orthopaedics and Traumatology*, Brussels, Belgium. Total pages 2.
65. Pavelka et al. (September 1999). "Safety Following Intra-articular Injections of NeuVisc™--Two Studies," *Fourth World Congress of the Osteo Arthritis Research Society International*, Vienna, Austria. total pages 2.
66. Piez, K. (1985). "Collagen", *Encyclopedia of Polymer Science and Engineering: Cellular Materials to Composites.* 2nd Ed., John Wiley & Sons. 3:699-727.
67. Rodeo, S. A. and Warren, R. F. (July 1996). "Meniscal Repair Using The Outside-To-Inside Technique," *Clin. Sports Med.* 15:469-481.
68. Rosenblatt, J. et al. (1989). "The Effect of Collagen Fiber Size Distribution on the Release Rate of Proteins from Collagen Matrices by Diffusion," *J. of Controlled Release* 9:195-203.
69. Rubin, A. L. et al. (February 1965). "Effects of Pepsin Treatment on the Interaction Properties of Tropocollagen Macromolecules," *Biochemistry* 4(2):181-190.
70. Shroeder-Tefft, J. A et al. (1997). "Collagen and Heparin Matrices for Growth Factor Delivery," *Controlled Release* 49:291-298.
71. Smith, I. et al. (1991). "Effects of Local Anesthesia on Recovery After Outpatient Arthroscopy," *Anesth. Analg.* 73:536-539.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

<p>Form PTO-1449</p> <p>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</p> <p><i>(Use several sheets if necessary)</i></p>		<table border="1"> <tr> <td>Docket Number 437252001200</td> <td>Application Number 10/082,443</td> </tr> <tr> <td colspan="2">Applicant</td> </tr> <tr> <td colspan="2">Mark R. ALVIS et al.</td> </tr> <tr> <td>Filing Date: February 22, 2002</td> <td>Group Art Unit: 1614</td> </tr> <tr> <td colspan="2">Mailing Date: May 9, 2002</td> </tr> </table>	Docket Number 437252001200	Application Number 10/082,443	Applicant		Mark R. ALVIS et al.		Filing Date: February 22, 2002	Group Art Unit: 1614	Mailing Date: May 9, 2002	
Docket Number 437252001200	Application Number 10/082,443											
Applicant												
Mark R. ALVIS et al.												
Filing Date: February 22, 2002	Group Art Unit: 1614											
Mailing Date: May 9, 2002												

72. Solanki, D.R. et al. (1992). "Serum Bupivacaine Concentrations After Intraarticular Injection for Pain Relief After Knee Arthroscopy," *Arthroscopy* 8:44-47.

73. Steffen, C. et al. (1975). "Collagen-Induced Acute Synovitis in Collagen-Immunized Rabbits," *A. Immun.-Forsch. Bd.* 150:432-446.

74. Summary of Product Characteristics: Chirocaine® (Manufacturer: Abbott): 2 pages total.

75. Wallace, D. G. et al. (1986). "Multiple Denaturational Transitions in Fibrillar Collagen," *Biopolymers* 25:1875-1893.

76. Wasudev, G. et al. (1990). "Blood Levels of Bupivacaine After Arthroscopy of the Knee Joint," *Arthroscopy* 6(1):40-42

77. Weiss, C. et al. (1986). "The Role of Na-hylan in Reducing Postsurgical Tendon Adhesions," *Bull. Hosp. Jt. Dis. Orthop. Inst.* 46:9-15.

78. Weiss, C. et al. (1987). "The Role of Na-hylan in Reducing Postsurgical Tendon Adhesions: Part 2," *Bull. Hosp. Jt. Dis. Orthop. Inst.* 47:31-39.

79. Whately, J. S. et al. (March 2000). "The Effect of an Exogenous Fibrin Clot on the Regeneration of the Triangular Fibrocartilage Complex: An In Vivo Experimental Study in Dogs," *Arthroscopy* 16:127-136.

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.